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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,962	11/29/2001	Robert Hanson	DOCUSY 3.0-007	4898

530 7590 01/20/2010

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EXAMINER	
COBANOGLU, DILEK B	
ART UNIT	PAPER NUMBER
3626	
MAIL DATE	DELIVERY MODE
01/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,962	HANSON ET AL.	
	Examiner	Art Unit	
	DILEK B. COBANOGLU	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,19-30,37-40 and 43-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,19-30,37-40 and 43-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment received on 9/30/2009. Claims 44-50 have been newly added. Therefore claims 16, 19-30, 37-40, 43-50 remain pending in this application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 16, 19-30, 38-49, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (hereinafter Walker) (U.S. Patent No. 5,651,775) in view of Brook et al. (hereinafter Brook) (U.S. Patent No. 6,170,746 B1).

A. Claim 16 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. providing a single source of a drug to be administered to a patient (Walker; abstract, col. 2, lines 7-19), wherein said single source of a drug includes an individual drug and an individual medical device, (Walker; abstract, col. 2, lines 28-34, col. 3, lines 35-41, col. 3, lines 8-16),

ii. associating a unique tracking code with said single source, wherein said unique tracking code is unique as to a said single source,

iii. providing data associated with said drug in said single source to be administered from providing of said single source containing said drug to disposal of said single source (Walker; abstract, col. 2, lines 7-19, col. 10, lines 56-65),

iv. disposing of said single source (Walker; col. 10, lines 56-65),

v. storing said data in association with said tracking code on a storage device, whereby the stored data may be altered while still being associated with the same unique tracking code, and

vi. retrieving the stored data from said storage device using said tracking code, wherein the stored data, retrieved by the tracking code from the storage device, tracks the preparation of said source containing said drug, administration of said drug from said source, and disposal of said source, wherein said unique tracking code conveys no information other than the identity of the tracking code.

Walker fails to expressly teach "associating a unique tracking code with said single source, wherein said unique tracking code is unique as to a said single source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "associating a unique tracking code with said single source, wherein said unique tracking code is unique as to a said single source" (Brook; abstract, col. 3, lines 15-24, col. 3, lines 32-40, col. 4, lines 14-19, col. 5, lines 48-54).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimizing the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

Walker fails to expressly teach "storing said data in association with said tracking code on a storage device, whereby the stored data may be altered while still being associated with the same unique tracking code" and "retrieving the stored data from said storage device using said tracking code, wherein the stored data tracks the administration of said drug from said source from providing of said source to said disposing of said source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook teaches these limitations in col. 3, lines 8-24, col. 3, lines 32-40.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimizing the manual entry of tracking data and automatically update the requisite

records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

Walker fails to expressly teach "retrieving the stored data from said storage device using said tracking code, wherein the stored data, retrieved by the tracking code from the storage device, tracks the preparation of said source containing said drug, administration of said drug from said source, and disposal of said source, wherein said unique tracking code conveys no information other than the identity of the tracking code". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "retrieving the stored data from said storage device using said tracking code, wherein the stored data, retrieved by the tracking code from the storage device, tracks the preparation of said source containing said drug, administration of said drug from said source, and disposal of said source, wherein said unique tracking code conveys no information other than the identity of the tracking code" (Brook; abstract, col. 3, lines 8-24, col. 3, lines 32-40, col. 5, lines 48-54, col. 6, lines 36-55 and col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as

disclosed by Brook with the motivation of minimizing the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

B. Claims 19-24 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 19-24 are rejected for the same reasons given in the previous Office Action, and incorporated herein.

C. Claims 25-26 have been amended to replace "source" with "medical device", and Applicant does not appear to argue the separate patentability of these claims. As such, claims 25-26 are rejected for the same reasons given in the previous Office Action, and incorporated herein.

D. The amendment made to claim 27 reflect the same changes made to claim 16, and therefore this claim is rejected for the same reasons given in the previous office action and the reasons given above for claim 16 and incorporated herein.

E. Claims 28-30 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 28-30 are rejected for the same reasons given in the previous Office Action, and incorporated herein.

F. Claims 38-39 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 38-39 are

rejected for the same reasons given in the previous Office Action, and incorporated herein.

G. Newly added claim 48 recites a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. preparation of a single source of a drug to be administered to a patient, wherein said single source of a drug is an individual syringe, affixing said single source in a cradle (Walker; abstract, col. 2, lines 28-34, col. 3, lines 35-41, col. 3, lines 8-16),

ii. providing a label having a bar code corresponding to a unique tracking code affixed to at least one of said source and said cradle, wherein said unique tracking code is unique as to said single source, identifying data associated with said drug in said single source and said patient,

iii. storing said data in association with said unique tracking code on a storage device (Walker; col. 5, lines 26-40, col. 13-47),

iv. administering a quantity of said drug contained in said source to a patient (Walker; col. 5, lines 26-40, col. 13-47),

v. disposing of said single source after administration of said drug to a patient (Walker; col. 10, lines 41-65),

vi. updating said data in association with the unique tracking code on said storage device, and

vii. retrieving said data from said storage device using said unique tracking code, wherein said data, retrieved by the tracking code from the storage device, tracks said source from preparation of said source containing said drug to disposing of said source, wherein said unique tracking code conveys no information other than the identity of the tracking code.

Walker fails to expressly teach “a label having a bar code corresponding to a unique tracking code affixed to at least one of said source and said cradle, wherein said unique tracking code is unique as to said single source,

identifying data associated with said drug in said single source and said patient,”. However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses this feature in abstract and col. 3, lines 15-24, col. 3, lines 32-40.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimize the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

Walker fails to expressly teach "updating said data in association with the unique tracking code on said storage device, and retrieving said data from said storage device using said unique tracking code, wherein said data, retrieved by the tracking code from the storage device, tracks said source from preparation of said source containing said drug to disposing of said source, wherein said unique tracking code conveys no information other than the identity of the tracking code". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "updating said data in association with the unique tracking code on said storage device, and retrieving said data from said storage device using said unique tracking code, wherein said data, retrieved by the tracking code from the storage device, tracks said source from preparation of said source containing said drug to disposing of said source, wherein said unique tracking code conveys no information other than the identity of the tracking code" (Brook; abstract, col. 3, lines 8-24, col. 3, lines 32-40, col. 5, lines 48-54, col. 6, lines 36-55 and col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as

disclosed by Brook with the motivation of minimize the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

H. Newly added claim 49 recites the method of claim 48, further comprising said single source including other markings other than said unique tracking code.

I. Newly added claim 50 recites the method of claim 49, wherein said other markings comprises written text, type written text, patient information, drug information, or other bar codes.

4. Claims 37, 40 and 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brook et al. (hereinafter Brook) (U.S. Patent No. 6,170,746 B1) in view of Walker et al. (hereinafter Walker) (U.S. Patent No. 5,651,775).

A. Claim 37 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. preparing a single source of a drug to be administered to a patient (Brook; col. 6, line 56 to col. 7, line 31), wherein said single source of a drug includes an individual syringe,

ii. associating a unique tracking code with said single source (Brook; col. 5, lines 48-54),

iii. providing first data associated with said tracking code relating to said drug in said single source to be administered (Brook; col. 5, lines 48-54),

iv. providing second data representing an amount of said drug in said single source administered to said patient from said single source associated with said tracking code (Brook; col. 7, lines 32-50, col. 8, lines 27-65),

v. providing third data associated with disposing of said single source (Brook; col. 6, lines 36-55, col. 10, line 51 to col. 11, line 12),

vi. storing said first, second and third data in association with said tracking code on a storage device (Brook; col. 6, lines 2-19),

vii. retrieving said first, second and third data from said storage device using said tracking code, whereby said first, second and third data associated with said tracking code, and retrieved by the tracking code from the storage device, tracks said single source containing said drug from said preparing of said source through administration of said drug to a patient to said disposal thereof (Brook; col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

Brook fails to expressly teach "single source of a drug includes an individual drug and an individual medical device". However, this feature is well known in the art, as evidenced by Walker.

In particular, Walker discloses "single source of a drug includes an individual drug and an individual medical device" (Walker; abstract, col. 2, lines 28-34, col. 3, lines 35-41, col. 3, lines 8-16).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Walker with the motivation of returning the unused drugs and therefore reducing of drug waste (Walker; col. 3, lines 9-14).

B. Claims 40 and 43 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 40 and 43 are rejected for the same reasons given in the previous Office Action, and incorporated herein.

C. Newly added claim 44 recites a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. providing a single source of a drug to be administered to a patient (Brook; col. 6, line 56 to col. 7, line 31), wherein said single source of a drug includes an individual syringe,

ii. associating a unique tracking code with said single source, wherein said unique tracking code is unique as to said single source (Brook; col. 5, lines 48-54),

iii. providing data associated with said single source to be administered from providing of said single source to disposal of said single source (Brook; col. 5, lines 48-54),

iv. storing said data in association with said tracking code on a storage device, whereby the stored data may be altered while still being associated with the same unique tracking code (Brook; col. 6, lines 2-19), and

v. retrieving the stored data from said storage device using said tracking code, wherein the stored data, retrieved by the tracking code from the storage device, tracks the single source from the preparation of said source to the disposal of said source (Brook; col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

Brook fails to expressly teach "said single source of a drug includes an individual syringe". However, this feature is well known in the art, as evidenced by Walker.

In particular, Walker discloses "said single source of a drug includes an individual syringe" (Walker; abstract, col. 2, lines 28-34, col. 3, lines 35-41, col. 3, lines 8-16).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Walker with the motivation of returning the unused

drugs and therefore reducing of drug waste (Walker; col. 3, lines 9-14).

D. Newly added claim 45 recites the method of claim 44, wherein said unique tracking code is written on a bar code (Brook; abstract, col. 3, lines 14-19).

E. Newly added claim 46 recites the method of claim 45, further comprising said single source including other markings other than said unique tracking code.

Brook fails to expressly teach "single source including other markings other than said unique tracking code". However, this feature is well known in the art, as evidenced by Walker.

In particular, Walker discloses "single source including other markings other than said unique tracking code" (Walker; figure 5A, col. 6, lines 20-36).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Walker with the motivation of the information being easily viewed by the operator (Walker; col. 6, lines 20-36).

F. Newly added claim 47 recites the method of claim 46, wherein said other markings comprises written text, type written text, patient information, drug information, or other bar codes.

Brook fails to expressly teach "other markings comprises written text, type written text, patient information, drug information, or other

bar codes". However, this feature is well known in the art, as evidenced by Walker.

In particular, Walker discloses "other markings comprises written text, type written text, patient information, drug information, or other bar codes" (Walker; figure 5A, col. 6, lines 20-36).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Walker with the motivation of the information being easily viewed by the operator (Walker; col. 6, lines 20-36).

Response to Arguments

5. Applicant's arguments filed 9/30/2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear.

A. In response to applicant's argument that "the combination of Walker and Brook is not proper since they are directed at very different applications and uses", the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Walker teaches a medication delivery and monitoring system, which is used to assure proper

identification and administration of prescribed drugs, to control access to drugs and to record drug distribution activities and producing standardized labeling and in packaging drug for distribution within a medical facility (Walker; title and col. 1, lines 54-67) and Brook teaches a system and method for tracking drugs in a hospital, where a host system having a memory for storing drug tracking records and automatically updates the drug tracking records from information transmitted by the portable scanning and printing system (Brook; title and col. 3, lines 15-24). The motivation to combine these two references would be to improve accuracy, speed and efficiency of the drug tracking as explained above in the rejection of claim 16.

B. In response to Applicant's argument about Brook does not teach "tracking an individual syringe or the like"; Examiner respectfully submits that Brook teaches "…the user scans **a barcode typically being located** on the shelf supporting the drug or **on a drug container**" in col. 4, lines 14-19; and …"multiple labels may be printed for application to **individual drug containers** if the drug is so packaged." In col. 9, lines 56-60.

C. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to Applicant's argument about Walker do not include "a central network and a tracking code"; Examiner respectfully

submits that Brook teaches a tracking code (barcode on the drug container) in col. 4, lines 14-19. The present invention does not recite “a central network” in the claims, but the claims recite “storing data in association with said tracking code on a storage device”. Examiner respectfully submits that Brook teaches “a host system having a memory for storing drug tracking records and automatically updates the drug tracking records from information transmitted by the portable scanning and printing system (Brook; title and col. 3, lines 15-24).

D. In response to Applicant’s argument about references do not teach “a single source, having a unique tracking code, wherein the unique tracking code conveys no other information than the identity of the unique tracking code itself"; Examiner respectfully submits that Brook teaches “…the portable scanning and printing system includes a memory for collecting data, a display, a printer and a number of input means including a barcode scanner, a keyboard or keypad, and a wireless communication interface. The wireless communication interface allows the portable scanning and printing system to communicate with a host system having a memory for storing drug tracking records wherein the host system automatically updates the drug tracking records from information transmitted thereto by the portable scanning and printing system.” In col. 3, lines 14-23. The Applicant continues to argue and states that Walker teaches tracking administration of a drug in a specific syringe, but the claimed invention is aimed at tracking a specific medical device. The present specification recites “the term “medical device” as used herein means any syringe application, IV ports, pill

containers, drug vials, drug ampules, non-injectable drugs and fluids, whether intravenously or otherwise, all of which can be monitored using the tracking code system of the present invention. Examiner respectfully submits that Walker teaches monitoring medication delivery using bar codes affixed to the syringe label cradle (Walker; col. 2, lines 7-19), also in figure 5 and 5A, it is obvious that Walker's label with barcode is affixed to a single syringe and syringe label cradle (or medical device), and therefore the information on the label and the barcode should be related to the single syringe and the drug inside of the syringe altogether.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

7. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DILEK B. COBANOGLU whose telephone number is (571)272-8295. The examiner can normally be reached on 8-4:30.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on 571-272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. B. C./
Examiner, Art Unit 3626
1/7/2010

/Robert Morgan/
Primary Examiner, Art Unit 3626